

### Remarks/Arguments

Claims 5-6, 49-51, 53, 55-60, and 66-74 are pending in this Application. In the Final Office Action mailed May 6, 2003, the Examiner:

1. restricted claims 68-74 to another eukaryotic virus pseudocapsid and method of making the same;
2. objected to claims 5, 6, 49, 55, 60, and 68-74 under 35 U.S.C. § 132 for introducing new matter;
3. rejected claims 1, 5, 6, 49, 55, 60, 68-74 under 35 U.S.C. § 112, first paragraph, as containing subject matter not described in the specification;
4. rejected claims 5-7, 49-55, and 60-65 under 35 U.S.C. § 112, second paragraph, as being indefinite;
5. rejected claim 6 under 35 U.S.C. § 112, second paragraph, for lack of sufficient antecedent basis;
6. rejected claims 5-7, 49-56, and 61-65 under 35 U.S.C. § 112, first paragraph, for not providing reasonable enablement;
7. rejected claims 5-7, 49, 51, 52, 53, 54, 55, and 60-65 under 35 U.S.C. § 102(b) as being anticipated by Baumert et al. (J. Virol 1998, Vol. 72, pp. 3827-3836);
8. rejected claims 5-7, 49-52, 54-55, and 61-65 under 35 U.S.C. § 102(b) as being anticipated by Yasui et al. (J. Virol 1998, Vol. 72, pp. 6048-6065);
9. rejected claims 5-7, 49-52, 54-55, and 61-65 under 35 U.S.C. § 102(b) as being anticipated by Liang et al. (WO 98/21338 A1);
10. rejected claims 5-6, 49-51, and 61-63 under 35 U.S.C. § 102(b) as being anticipated by Wengler et al. (Virol. 1982, Vol. 118, pp.401-411);
11. rejected claims 5-7, 49-52, 54-55, and 61-65 under 35 U.S.C. § 102(a) as being anticipated by Falco et al. (Tissue & Cell, 1999, Vol. 31, pp. 17-125);
12. rejected claims 6, 49, 55, 60, and 66-67 under 35 U.S.C. § 112, second paragraph, as being indefinite;
13. rejected claims 6, 49, 51, 53, 55, and 60 under 35 U.S.C. § 112, first paragraph, as containing subject matter not described in the specification;

14. rejected claim 60 under 35 U.S.C. § 102(b) as being anticipated by Segre et al. (J. Gen. Virol. 1997, Vol 78, pp. 1861-1866); and
15. rejected claim 60 under 35 U.S.C. § 102(b) as being anticipated by Yamshchikov et al. (Virol. 1993, Vol 192, pp. 38-51).

Applicant would like to thank the Examiner for the telephone interview held on June 5, 2003, and for discussing the Office Action in more detail. Applicant also address the basis for each of the Examiner's withdrawal of claims, objections and rejections below.

***Election/Restrictions***

The Examiner states, "Newly added claims 68-74 are directed to another eukaryotic virus pseudocapsid and a method of making the same, which are structural distinct from the one in the elected group." Applicant respectfully disagrees with the Examiner's interpretation of the newly added claims and submit that claims 68-74 fall within the invention classified by the Examiner in Paper No. 8 as Group II, claims 5-7, "drawn to a eukaryotic pseudo-nucleocapsid, classified in the class 530, subclass 826," and defined by the Patent Classification as "cross-reference art collection for peptides or proteins which are separated from virus."

Applicant respectfully believes that claims 69-74 read on the elected invention. The Examiner has not provided reasons and/or examples to support conclusions that the inventions are independent or distinct as claimed. MPEP § 803. Nor has the Examiner established that a serious burden would be imposed on the Examiner if restriction were not required. In particular, the Examiner failed to show that there is a separate classification for claims 69-74 and that separate fields of searching would be required. Finally, the Examiner has not established that claims 69-74 have achieved a separate status in the art, even though they are classified together. MPEP § 802. As such, Applicant respectfully requests reconsideration and withdrawal of the restriction/election requirement. Applicant also requests withdrawal of claim 68.

***Claims Objections under 35 U.S.C. § 132 - Claims 5, 6, 49, 55, 60, 68-74***

The Examiner objected to claim 5, lines 6-7, "after which no additional purification step is required," because it introduces new matter into the disclosure. Applicant respectfully submits

that the added material in amended claim 5 is supported by the original disclosure as shown below:

In one example, purified recombinant HCV capsid protein (HCVC124) was diluted in assembly buffer (100 mM KAcetate, 1.7 mM MgAcetate, 25 mM HEPES pH 7.4, 5 mM DTT) to a final concentration of approximately 1mg/ml or 0.1mM. Oligonucleotides (e.g., tRNA<sub>Phe</sub>, SIGMA) are resuspended in assembly buffer to a final relative ratio of 1/10 nucleotide to protein concentration. These amounts were found to be an example of an effective protein polynucleotide ratio. Equal volumes of the capsid protein and the RNA solutions were mixed together and incubated at 30°C for 10 minutes prior to transfer to 4°C for at least approximately 15 minutes before analysis. Electron microscopy of negative stained preparations comprising the mixture of HCVC124 capsid protein and tRNA showed the formation of spheroid LSVL particles (data not shown). [pg. 42, ll. 1-16]

Furthermore, the LSVL particles form the basis of assays to identify inhibitors of HCV assembly and/or disassembly spontaneously formed in vitro. [pg. 36, ll. 7-10]

The Examiner objected to claim 6, line 2: "homologous sequence of a core protein from a member of the flavivirus family." Applicant has amended claim 6 and no longer includes the objected to limitation.

Claim 6, 55, and 60 have been amended, and thus the objections to these claims have been obviated. Applicant requests cancellation of claim 49.

The Examiner objected to claims 68-74, stating "the claimed invention [is] drawn to a pseudonucleocapsid with a sequence comprising a hepatic C core protein and a homologous sequence of a core protein from a member of the flavivirus family mixed with a polynucleotide RNA of at least 10 nucleotides that form [a] stem loop structure were not supported by the disclosure as the Application was originally filed." Applicant points out that the application as originally filed included Claim 2: "The construct of claim 1, wherein said capsid polypeptide is a flavivirus capsid polypeptide" and Claim 6: "The virus pseudo-nucleocapsid of claim 5, wherein said viral capsid polypeptide is a flavivirus capsid polypeptide." Applicant has also amended claims 69, 71, and 74. Applicant submits that amended claims 69, 71, 72, and 74 and claim 73 are supported by the original disclosure (e.g., pg. 9, ll. 5-14; pg. 11, ll. 14-20; pg. 12, ll. 12-20; pg. 39, ll. 13-20; pg. 40, ll. 16-21; pg. 42, ll. 1-16,).

In light of the above amendments, Applicant respectfully requests allowance of amended claims 5, 6, 55, 60, 69, 71, 72 and 74 as well as claim 73. Applicant requests withdrawal of claims 68 and 70.

***Claims Rejections under 35 U.S.C. § 112, first paragraph - Claims 1, 5, 6, 49, 55, 60, 68-74***

The Examiner rejected claims 1, 5, 6, 49, 55, 60, 68-74 under 35 U.S.C. § 112, first paragraph, as containing subject matter not described in the specification in such a way as to reasonably convey one of skill in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant submits that claim 1 is not a pending claim. Applicant respectfully submits entry and requests allowance of amended claims 5, 6, 55, 60, 69, 71, and 74 as well as claims 72-73 depending from amended claim 74 in light of the amendments and arguments provided above.

***Claims Rejections under 35 U.S.C. § 112, second paragraph - Claims 5-7, 49-55, 60-65***

The Examiner rejected claims 5-7, 49-55, and 60-65 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter the applicant regards as the invention. Applicant has amended claims 5, 6, 55, and 60 and submits that rejections of these claims, as well as claims 50 and 51 depending from amended claim 5, have been obviated by the present amendments. Applicant requests the cancellation of claims 7, 52-54, and 61-65.

***Claims Rejections under 35 U.S.C. § 112, first paragraph - Claims 5-7, 49-56, 61-65***

The Examiner rejected claims 5-7, 49-56, and 61-65 under 35 U.S.C. § 112, first paragraph. Applicant has amended claim 5. Support for and enablement of amended claim 5 can be found throughout the Specification, such as pg. 40, ll. 4-16 and pg. 43, ll. 1-16. As such, amended claim 5, namely a virus pseudo-nucleocapsid consisting of the viral capsid polypeptide, wherein the viral capsid polypeptide is SEQ ID NO:1 and a tRNA molecule is adequately taught by the Specification. Applicant respectfully submits entry and requests allowance of amended claims 5, 6, and 55 as well as claims 50 and 51 in light of these amendments.

***Claims Rejections under 35 U.S.C. § 102(a) and 102(b)***

The Examiner rejected claims 5-7, 49, 51, 52, 53, 54, 55, and 60-65 under 35 U.S.C. § 102(b) as being anticipated by Baumert et al. (J. Virol 1998, Vol. 72, pp. 3827-3836). Applicant has amended claim 5 and includes limitations considered enabling by the Examiner, namely a viral pseudo-nucleocapsid consisting of "SEQ ID NO:1" and "tRNA." As such, Applicant respectfully requests the rejection to claim 5 and all claims depending from claim 5, namely claims 6, 50-51, 55, and 60 be withdrawn under 35 U.S.C. § 102(b).

The Examiner rejected claims 5-7, 49-52, 54-55, and 61-65 under 35 U.S.C. § 102(b) as being anticipated by Yasui et al. (J. Virol 1998, Vol. 72, pp. 6048-6065). Applicant submits that Yasui et al. does not disclose the product or process of forming virus pseudo-nucleocapsids. Yasui et al. is merely an analysis of "maturation and subcellular localization of hepatitis C virus (HCV) core protein" using "vaccinia virus expression system and CHO cell lines stably transformed with HCV cDNA." In order for a rejection under 35 U.S.C. § 102 to be proper, the cited reference must teach each and every aspect of the claimed invention either explicitly or impliedly. See MPEP § 2131. A single reference must identically disclose every element of the claimed invention. *Corning Glass Works v. Sumitomo Electric*, 9 U.S.P.Q. 2d 1962, 1965 (Fed. Cir. 1989). A reference that excludes a claimed element, no matter how insubstantial or obvious, is enough to negate anticipation. *Connell v. Sears, Roebuck & Co.*, 220 U.S.P.Q. 193, 198 (Fed. Cir. 1983). Yasui et al. does not disclose a *virus pseudo-nucleocapsid* consisting of a viral capsid polypeptide, *wherein the viral capsid polypeptide is SEQ ID NO:1*; and a *tRNA molecule*. As such, Yasui et al. cannot anticipate Applicant's instant invention.

The Examiner rejected claims 5-7, 49-52, 54-55, and 61-65 under 35 U.S.C. § 102(b) as being anticipated by Liang et al. (WO 98/21338 A1), rejected claims 5-6, 49-51, and 61-63 under 35 U.S.C. § 102(b) as being anticipated by Wengler et al. (Virol. 1982, Vol. 118, pp.401-411), and rejected claims 5-7, 49-52, 54-55, and 61-65 under 35 U.S.C. § 102(a) as being anticipated by Falco et al. (Tissue & Cell, 1999, Vol. 31, pp. 17-125). As discussed above, Applicant has amended claim 5, believed to no longer anticipate Liang et al., Wengler et al., or Falco et al. As such, Applicant respectfully requests the rejection to claim 5 and all claims depending from claim 5, namely claims 6, 50-51, 55, and 60 be withdrawn.

***Claims Rejections under 35 U.S.C. § 112, second paragraph - Claims 6, 49, 55, 60, 66-67***

The Examiner rejected claims 6, 49, 55, 60, and 66-67 under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant has amended claims 6, 55, and 60 and request withdrawal of the rejections. Applicant requests cancellation of claims 49 and 67 and withdrawal of claim 66.

***Claims Rejections under 35 U.S.C. § 112, first paragraph - Claims 6, 49, 51, 53, 55, 60***

The Examiner rejected claims 6, 49, 51, 53, 55, and 60 under 35 U.S.C. § 112, first paragraph, as containing subject matter not described in the specification. Applicant has amended claims 6, 55, and 60 and claim 51 that now include enabling disclosures as previously discussed. Applicant requests cancellation of claims 49 and 53.

***Claims Rejections under 35 U.S.C. § 102(b) - Claim 60***

The Examiner rejected claim 60 under 35 U.S.C. § 102(b) as being anticipated by Segrue et al. (J General Virol. 1997, Vol 78, pp. 1861-1866) and as being anticipated by Yamshchikov et al. (Virol. 1993, Vol 192, pp. 38-51). Applicant submits that neither Segrue et al. nor Yamshchikov et al. disclose a *virus pseudo-nucleocapsid* consisting of a viral capsid polypeptide, *wherein the viral capsid polypeptide is SEQ ID NO.:*; and a *tRNA molecule* as required by claim 5, from which claim 60 depends. As such, neither Segrue et al. nor Yamshchikov et al. can anticipate Applicant's instant invention. Applicant respectfully requests the rejection to amended claim 60 be withdrawn under 35 U.S.C. § 102(b).

**Conclusion**

In light of the Amendments and Remarks/Arguments presented above, Applicants respectfully submit that the Application is in allowable form. Applicants respectfully request that a timely Notice of Allowance be issued in this case.

It is believed that no additional fees are due at this time. If this is incorrect, Applicants hereby authorize the Commissioner to charge any fees, other than the issue fees, that may be required by this paper to Deposit Account 07-0153.

The Examiner is invited to call the undersigned if it appears that such communication would advance the current application to issue.

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Respectfully submitted,

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